EXPLANATORY MEMORANDUM TO THE

MEDICINES (SALE OR SUPPLY) (MISCELLANEOUS AMENDMENTS) REGULATIONS 2005

2005 No. 1520

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), part of the Department of Health, and is laid before Parliament by Command of Her Majesty.

2. **Description**

2.1 These Regulations amend the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 and the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 to extend supplementary prescribing to registered optometrists. They update the reference to "registered ophthalmic optician" in the Miscellaneous Provisions Regulations and allow the sale of a specific prescription only medicine on a wholesale basis to an additional supply optometrist. The Regulations also amend the maximum pack size of Bisacodyl tablets on general sale. Finally, they update the definition of a supplementary prescriber contained in the Medicines (Child Safety) Regulations 2003.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None.

4. **Legislative Background**

4.1 These Regulations amend the Medicines for Human use (Marketing Authorisations Etc) Regulations 1994 which, among other matters, implement European Community provisions relating to marketing authorisations for medicinal products. In particular, they require all medicinal products which are placed on the market to hold a marketing authorisation granted by the MHRA. There are exemptions from this requirement for medicinal products supplied in response to a bona fide unsolicited order formulated in accordance with the specification of a doctor, dentist or supplementary prescriber for use by their individual patients.

4.2 Supplementary prescribing is an arrangement whereby after a diagnosis by a doctor or dentist (the independent prescriber), the supplementary prescriber can prescribe medicines as part of a Clinical Management Plan agreed with the independent prescriber for an individual patient. Currently, registered nurses, midwives, pharmacists, podiatrists, physiotherapists and diagnostic and therapeutic radiographers can act as supplementary prescribers. The amending Regulations will extend the definition of supplementary prescriber in the Marketing Authorisation Regulations to include

registered optometrists. This is in line with related legislation due to be implemented at the same time.

4.3 The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (the Sale or Supply Regulations) impose various restrictions on the sale and supply of medicinal products. The amending Regulations will amend the definition of a supplementary prescriber in the Sale or Supply Regulations to include registered optometrists. The current references to "registered ophthalmic optician" will also be replaced by the term "registered optometrist" to reflect changes due to be implemented by the Opticians Act 1989 (Amendment) Order 2005.

4.4 The Sale or Supply Regulations set out restrictions on the classes of person who can be sold prescription only medicines ("POMs") on a wholesale basis. There are exemptions from these restrictions for the sale of specified POMs to registered optometrists. The amending Regulations will allow additional supply optometrists (that is, those optometrists who have completed additional training and are accredited by the General Optical Council) to be sold Thymoxamine hydrochloride via wholesale.

4.5 The Sale or Supply Regulations also set out conditions relating to the quantity of certain medicines which can be sold to the public from non-pharmacy retail outlets (General Sale List medicines). Under the Regulations, the maximum pack size of Bisacodyl tablets available from such outlets is 50 tablets. The amending Regulations will decrease this to 40 tablets.

4.6 Finally, the current definition of a supplementary prescriber contained in the Medicines (Child Safety) Regulations 2003 only covers nurses and pharmacists. The amending Regulations will update the definition to include all the groups of health professional who can act as supplementary prescribers.

5. **Extent**

5.1 This instrument applies to all of the United Kingdom.

6. **European Convention on Human Rights**

6.1 Not applicable.

7. **Policy Background**

7.1 Extending and updating the definition of supplementary prescribing and replacing the term "registered ophthalmic optician" with "registered optometrist" ensures consistency with other medicines legislation. The amendment relating to additional supply optometrists is in line with concurrent amendments to medicines legislation which will allow suitably trained and accredited optometrists access to an extended range of medicines and is intended to enhance patient care.

The change in the pack size of Bisacodyl tablets corrects an error contained in a previous amending order to the principal Regulations which came into force on 7 April.

7.2 The principals of extending supplementary prescribing and introducing specific provisions for additional supply optometrists were subject to public consultation and advice to ministers by the Committee on Safety of Medicines. Detailed analyses of the outcome of the public consultations have been published on the MHRA website: www.mhra,gov.uk However, as an example, for supplementary prescribing, the vast majority of responses (154 out of 157) were supportive.

8. **Impact**

8.1 A Regulatory Impact Assessment has been prepared for the proposals relating to supplementary prescribing.

8.2 The impact on the public sector is to benefit patients.

9. **Contact**

9.1 Anne Ryan at the MHRA, tel 0207 084 2392 or e-mail: anne.ryan@mhra.gsi.gov.uk can answer any queries regarding the instrument.